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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,056	12/19/2001	Karen Reue	407T-898010US	2961

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,056	REUE ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *8,9,14,15,17,20,21 and 26-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-13,16,18,19 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6//24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-25 and species election of "nucleic acids", filed on November 12, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The following claims read the elected invention and species: claims 1-7, 10-13, 16, 18, 19, and 22-25. Claims 8, 9, 14, 15, 17, 20, 21, and 26-63 have been withdrawn from consideration as being drawn to a non-elected.

Specification

2. The disclosure is objected to because of the following informalities:

(a) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at paragraph 0228. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7, 10-13, 16, 18, 19, 22-25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-7, 10-13, 16, 18, 19, 22-25 is indefinite at vague at the recitation of *"Lpin1"* and "lipin" because it is not clear from the specification or claims what constitutes "Lpin1 gene" or

"lipin". Additionally, if cannot be determined if the "*Lpin1* gene" or "lipin" is the same or different from the fatty liver dystrophy gene. Clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 10-13, 16, 18, 19, 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Klingenspor et al. (The Journal of Biological Chemistry, Vol. 274, No. 33, pages 23078-23084, August 1999). Note** The preceding rejection is based on the fact that the specification and claims do not clearly distinguish between the Lpin1 gene and/or *fld* gene. The limitation "Lpin1" is clearly not defined in the claims or specification. Therefore, for the purpose of application of prior art, the claim limitation "Lpin1" and "lipin" are being interpreted as "*fld*" or "*lfld1*". Regarding claims 1-5, 7, 10-13, 16, 18, 19, 22-25 Klingenspor et al. teach a method for screening for an agent that affects adipose tissue development, said method comprising: contacting a cell comprising a fatty liver dystrophy (*fld*) gene with a test agent; and detecting a change in the expression or activity of the *fld* gene product as compared to the expression or activity of a *fld* gene product in a cell that is contacted with the test agent at a lower concentration, wherein said lower concentration is the absence of said test agent, and wherein a difference in the expression or activity of *fld* indicates that said agent affects adipose tissue development. Klingenspor et al. The reference further teaches wherein the amount of *fld* gene product is detected by detecting *fld* mRNA in a sample and wherein said level of mRNA is

measured by hybridizing said mRNA to an oligonucleotide sequence that specifically hybridizes to the *fld* nucleic acid and wherein said hybridizing is according a method consisting of Northern blot or a nucleic acid amplification reaction (see "abstract" and section entitle "Experimental Procedures", and page 23080, col. 2, lines 35-49). Klingenspor et al also teach wherein the test agents which binds *fld* nucleic acid are recorded in a database of candidate agents that may or may not alter adipose tissue development (table 1). Therefore, Klingenspor et al teach the limitations of claims 1-5, 7, 10-13, 16, 18, 19, 22-25 of the instant invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klingenspor et al as previously applied above in view of Felder et al. (US 6,232,066 B1, May 15, 2001). Regarding claim 6, Klingenspor et al. teach a method for screening for an agent that affects

adipose tissue development, said method comprising: contacting a cell comprising a fatty liver dystrophy (*fld*) gene with a test agent; and detecting a change in the expression or activity of the *fld* gene product as compared to the expression or activity of a *fld* gene product in a cell that is contacted with the test agent at a lower concentration, wherein said lower concentration is the absence of said test agent, and wherein a difference in the expression or activity of *fld* indicates that said agent affects adipose tissue development. The reference differs from the instant invention that Klingenspor et al. do not teach wherein a probe array is used in the screening method for detecting expression of the *fld* gene. However, the use of probe arrays in methods for screening of candidate agents that affect a disease state or condition is well known and commonly used in the prior art. For example, in a general teaching Felder et al. teach the use of probe arrays which specifically hybridizes to a desired target agent. Felder et al. teach that the use of probe arrays in screening assays are advantageous because they allow for high throughput screening procedures for obtaining information about either the probes or the target molecule (col. 1, lines 31-33). Likewise, Felder et al teach that such screening assays with probe arrays provides the ability to perform simultaneously a wide variety of biological assays and do very many assays at once, thus allowing for flexibility and reusability (col. 2, lines 30-49). Therefore, in view of the foregoing, one of ordinary skill in the art would have been motivated at the time the claimed invention was made to have modified the screening method of Klingenspor et al to encompass a probe array specific for the *fld* gene. One of ordinary skill in the art would have been motivated to do for the advantages taught by Felder et al. that screening assays with probe arrays provides the ability to perform simultaneously a wide variety of biological assays and do very many assays at once, thus allowing for flexibility and reusability.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

Cynthia Wilder

CYNTHIA WILDER
PATENT EXAMINER
1/30/04